

## AMENDMENTS TO THE CLAIMS

10/501272  
DT04 Rec'd PCT/PTO 09 JUL 2004

Please amend claims 3, 4, 5, 6, 7, 8, 9 and 10 and add new claims 11-43 as

follows:

1. (Original) A pharmaceutical formulation for use in repelling and/or killing human head lice comprising a solution of Neem Oil and a surfactant.
2. (Original) A formulation as claimed in claim 1, wherein the solution comprises from about 1% w/w to about 1.25% w/w of Neem Oil and from about 0.2% to about 0.3% w/w of surfactant.
3. (Currently amended) A formulation as claimed in claim 1 ~~or claim 2~~, wherein the surfactant is cetrimonium chloride.
4. (Currently amended) A formulation as claimed in ~~any one of claims 1, 2, or 3~~, wherein the cetrimonium chloride is present in the composition at about 0.25% w/w of the compound.
5. (Currently amended) A formulation as claimed in ~~any one of claims 1 to 4~~, wherein the composition further comprises trace triethanolamine in an amount of about ~~approximately~~ 0.1% to 0.06% w/w of the composition.
6. (Currently amended) A formulation as claimed in ~~any one of claims 1 to 5~~, wherein the composition further comprises isopropyl alcohol.
7. (Currently amended) A formulation as claimed in ~~any one of claims 1 to 6~~, wherein the solution further comprises either ethyl alcohol or light liquid paraffin.
8. (Currently amended) A formulation as claimed in ~~any one of claims 1 to 7~~, wherein the solution comprises the following formulation

Aqua (water) – 91.155%;

Cetearyl alcohol – 4%;

Glyceryl stearate – 2%;

Melia Azadirachta seed oil (Neem Oil) – 1%;

Propylene glycol – 0.675%;

Cetrimonium chloride 26% – 0.26%;

Melaleuca Alternifolia (Tea Tree) leaf oil – 0.25%;  
 Lavandula Angustifolia (Lavender) oil – 0.25%;  
 Urtica Dioica (Nettle) extract – 0.2%;  
 Methylparaben & Propylparaben & Ethylparaben – 0.15%;  
 Thymus Vulgaris (Thyme) extract – 0.05%; and  
 Tethanolamine – 0.01%.

9. (Currently amended) A formulation as claimed in ~~any one of claims 1 to 7~~, wherein the solution comprises the following formulation:

Aqua (water) – 91.105%;  
 Cetearyl alcohol – 4%;  
 Glyceryl stearate – 2%;  
 Melia Azadirachta seed oil (Neem Oil) – 1%;  
 Propylene glycol – 0.675%;  
 Cetrimonium chloride 26% – 0.26%;  
 Melaleuca Alternifolia (Tea Tree) leaf oil – 0.25%;  
 Lavandula Angustifolia (Lavender) oil – 0.25%;  
 Urtica Dioica (Nettle) extract – 0.2%;  
 Methylparaben & Propylparaben & Ethylparaben – 0.15%;  
 Thymus Vulgaris (Thyme) extract – 0.05%; and  
 Tethanolamine – 0.06%.

10. (Currently amended) The user of a formulation as per ~~any of the preceding claims 1~~ for the manufacture of a medicament for the prevention and treatment of head lice infestation in humans.

11. (New) A formulation as claimed in claim 2, wherein the surfactant is cetrimonium chloride.

12. (New) A formulation as claimed in claim 2, wherein the cetrimonium chloride is present in the composition at about 0.25% w/w of the compound.

13. (New) A formulation as claimed in claim 3, wherein the cetrimonium chloride is present in the composition at about 0.25% w/w of the compound.
14. (New) A formulation as claimed in claim 4, wherein the composition further comprises trace triethanolamine in an amount of about 0.1% to 0.06% w/w of the composition.
15. (New) A formulation as claimed in any one of claim 2, wherein the composition further comprises isopropyl alcohol.
16. (New) A formulation as claimed in any one of claim 3, wherein the composition further comprises isopropyl alcohol.
17. (New) A formulation as claimed in any one of claim 4, wherein the composition further comprises isopropyl alcohol.
18. (New) A formulation as claimed in any one of claim 5, wherein the composition further comprises isopropyl alcohol.
19. (New) A formulation as claimed in any one of claim 2, wherein the solution further comprises either ethyl alcohol or light liquid paraffin.
20. (New) A formulation as claimed in any one of claim 3, wherein the solution further comprises either ethyl alcohol or light liquid paraffin.
21. (New) A formulation as claimed in any one of claim 4, wherein the solution further comprises either ethyl alcohol or light liquid paraffin.
22. (New) A formulation as claimed in any one of claim 5, wherein the solution further comprises either ethyl alcohol or light liquid paraffin.
23. (New) A formulation as claimed in any one of claim 6, wherein the solution further comprises either ethyl alcohol or light liquid paraffin.
24. (New) A formulation as claimed in claim 2, wherein the solution comprises the following formulation:

Aqua (water) – 91.155%;

Cetearyl alcohol – 4%;

Glyceryl stearate – 2%;

Melia Azadirachta seed oil (Neem Oil) – 1%;

Propylene glycol – 0.675%;  
 Cetrimonium chloride 26% – 0.26%;  
 Melaleuca Alternifolia (Tea Tree) leaf oil – 0.25%;  
 Lavandula Angustifolia (Lavender) oil – 0.25%;  
 Urtica Dioica (Nettle) extract – 0.2%;  
 Methylparaben & Propylparaben & Ethylparaben – 0.15%;  
 Thymus Vulgaris (Thyme) extract – 0.05%; and  
 Tethanolamine – 0.01%.

25. (New) A formulation as claimed in claim 3, wherein the solution comprises the following formulation:

Aqua (water) – 91.155%;  
 Cetearyl alcohol – 4%;  
 Glyceryl stearate – 2%;  
 Melia Azadirachta seed oil (Neem Oil) – 1%;  
 Propylene glycol – 0.675%;  
 Cetrimonium chloride 26% – 0.26%;  
 Melaleuca Alternifolia (Tea Tree) leaf oil – 0.25%;  
 Lavandula Angustifolia (Lavender) oil – 0.25%;  
 Urtica Dioica (Nettle) extract – 0.2%;  
 Methylparaben & Propylparaben & Ethylparaben – 0.15%;  
 Thymus Vulgaris (Thyme) extract – 0.05%; and  
 Tethanolamine – 0.01%.

26. (New) A formulation as claimed in claim 4, wherein the solution comprises the following formulation:

Aqua (water) – 91.155%;  
 Cetearyl alcohol – 4%;

Glyceryl stearate – 2%;  
 Melia Azadirachta seed oil (Neem Oil) – 1%;  
 Propylene glycol – 0.675%;  
 Cetrimonium chloride 26% – 0.26%;  
 Melaleuca Alternifolia (Tea Tree) leaf oil – 0.25%;  
 Lavandula Angustifolia (Lavender) oil – 0.25%;  
 Urtica Dioica (Nettle) extract – 0.2%;  
 Methylparaben & Propylparaben & Ethylparaben – 0.15%;  
 Thymus Vulgaris (Thyme) extract – 0.05%; and  
 Tethanolamine – 0.01%.

27. (New) A formulation as claimed in claim 5, wherein the solution comprises the following formulation:

Aqua (water) – 91.155%;  
 Cetearyl alcohol – 4%;  
 Glyceryl stearate – 2%;  
 Melia Azadirachta seed oil (Neem Oil) – 1%;  
 Propylene glycol – 0.675%;  
 Cetrimonium chloride 26% – 0.26%;  
 Melaleuca Alternifolia (Tea Tree) leaf oil – 0.25%;  
 Lavandula Angustifolia (Lavender) oil – 0.25%;  
 Urtica Dioica (Nettle) extract – 0.2%;  
 Methylparaben & Propylparaben & Ethylparaben – 0.15%;  
 Thymus Vulgaris (Thyme) extract – 0.05%; and  
 Tethanolamine – 0.01%.

28. (New) A formulation as claimed in claim 6, wherein the solution comprises the following formulation:

Aqua (water) – 91.155%;  
Cetearyl alcohol – 4%;  
Glyceryl stearate – 2%;  
Melia Azadirachta seed oil (Neem Oil) – 1%;  
Propylene glycol – 0.675%;  
Cetrimonium chloride 26% – 0.26%;  
Melaleuca Alternifolia (Tea Tree) leaf oil – 0.25%;  
Lavandula Angustifolia (Lavender) oil – 0.25%;  
Urtica Dioica (Nettle) extract – 0.2%;  
Methylparaben & Propylparaben & Ethylparaben – 0.15%;  
Thymus Vulgaris (Thyme) extract – 0.05%; and  
Tethanolamine – 0.01%.

29. (New) A formulation as claimed in claim 7, wherein the solution comprises the following formulation:

Aqua (water) – 91.155%;  
Cetearyl alcohol – 4%;  
Glyceryl stearate – 2%;  
Melia Azadirachta seed oil (Neem Oil) – 1%;  
Propylene glycol – 0.675%;  
Cetrimonium chloride 26% – 0.26%;  
Melaleuca Alternifolia (Tea Tree) leaf oil – 0.25%;  
Lavandula Angustifolia (Lavender) oil – 0.25%;  
Urtica Dioica (Nettle) extract – 0.2%;  
Methylparaben & Propylparaben & Ethylparaben – 0.15%;  
Thymus Vulgaris (Thyme) extract – 0.05%; and  
Tethanolamine – 0.01%.

30. (New) A formulation as claimed in claim 2, wherein the solution comprises the following formulation:

Aqua (water) – 91.105%;  
Cetearyl alcohol – 4%;  
Glyceryl stearate – 2%;  
Melia Azadirachta seed oil (Neem Oil) – 1%;  
Propylene glycol – 0.675%;  
Cetrimonium chloride 26% – 0.26%;  
Melaleuca Alternifolia (Tea Tree) leaf oil – 0.25%;  
Lavandula Angustifolia (Lavender) oil – 0.25%;  
Urtica Dioica (Nettle) extract – 0.2%;  
Methylparaben & Propylparaben & Ethylparaben – 0.15%;  
Thymus Vulgaris (Thyme) extract – 0.05%; and  
Tethanolamine – 0.06%.

31. A formulation as claimed in claim 3, wherein the solution comprises the following formulation:

Aqua (water) – 91.105%;  
Cetearyl alcohol – 4%;  
Glyceryl stearate – 2%;  
Melia Azadirachta seed oil (Neem Oil) – 1%;  
Propylene glycol – 0.675%;  
Cetrimonium chloride 26% – 0.26%;  
Melaleuca Alternifolia (Tea Tree) leaf oil – 0.25%;  
Lavandula Angustifolia (Lavender) oil – 0.25%;  
Urtica Dioica (Nettle) extract – 0.2%;  
Methylparaben & Propylparaben & Ethylparaben – 0.15%;

Thymus Vulgaris (Thyme) extract – 0.05%; and  
Tethanolamine – 0.06%.

32. A formulation as claimed in claim 4, wherein the solution comprises the following formulation:

Aqua (water) – 91.105%;  
Cetearyl alcohol – 4%;  
Glyceryl stearate – 2%;  
Melia Azadirachta seed oil (Neem Oil) – 1%;  
Propylene glycol – 0.675%;  
Cetrimonium chloride 26% – 0.26%;  
Melaleuca Alternifolia (Tea Tree) leaf oil – 0.25%;  
Lavandula Angustifolia (Lavender) oil – 0.25%;  
Urtica Dioica (Nettle) extract – 0.2%;  
Methylparaben & Propylparaben & Ethylparaben – 0.15%;  
Thymus Vulgaris (Thyme) extract – 0.05%; and  
Tethanolamine – 0.06%.

33. A formulation as claimed in claim 5, wherein the solution comprises the following formulation:

Aqua (water) – 91.105%;  
Cetearyl alcohol – 4%;  
Glyceryl stearate – 2%;  
Melia Azadirachta seed oil (Neem Oil) – 1%;  
Propylene glycol – 0.675%;  
Cetrimonium chloride 26% – 0.26%;  
Melaleuca Alternifolia (Tea Tree) leaf oil – 0.25%;  
Lavandula Angustifolia (Lavender) oil – 0.25%;



Urtica Dioica (Nettle) extract – 0.2%;

Methylparaben & Propylparaben & Ethylparaben – 0.15%;

Thymus Vulgaris (Thyme) extract – 0.05%; and

Tethanolamine – 0.06%.

34. A formulation as claimed in claim 6, wherein the solution comprises the following formulation:

Aqua (water) – 91.105%;

Cetearyl alcohol – 4%;

Glyceryl stearate – 2%;

Melia Azadirachta seed oil (Neem Oil) – 1%;

Propylene glycol – 0.675%;

Cetrimonium chloride 26% – 0.26%;

Melaleuca Alternifolia (Tea Tree) leaf oil – 0.25%;

Lavandula Angustifolia (Lavender) oil – 0.25%;

Urtica Dioica (Nettle) extract – 0.2%;

Methylparaben & Propylparaben & Ethylparaben – 0.15%;

Thymus Vulgaris (Thyme) extract – 0.05%; and

Tethanolamine – 0.06%.

35. A formulation as claimed in claim 7, wherein the solution comprises the following formulation:

Aqua (water) – 91.105%;

Cetearyl alcohol – 4%;

Glyceryl stearate – 2%;

Melia Azadirachta seed oil (Neem Oil) – 1%;

Propylene glycol – 0.675%;

Cetrimonium chloride 26% – 0.26%;

Melaleuca Alternifolia (Tea Tree) leaf oil – 0.25%;  
Lavandula Angustifolia (Lavender) oil – 0.25%;  
Urtica Dioica (Nettle) extract – 0.2%;  
Methylparaben & Propylparaben & Ethylparaben – 0.15%;  
Thymus Vulgaris (Thyme) extract – 0.05%; and  
Tethanolamine – 0.06%.

36. (New) The user of a formulation as per claim 2 for the manufacture of a medicament for the prevention and treatment of head lice infestation in humans.

37. (New) The user of a formulation as per claim 3 for the manufacture of a medicament for the prevention and treatment of head lice infestation in humans.

38. (New) The user of a formulation as per claim 4 for the manufacture of a medicament for the prevention and treatment of head lice infestation in humans.

39. (New) The user of a formulation as per claim 5 for the manufacture of a medicament for the prevention and treatment of head lice infestation in humans.

40. (New) The user of a formulation as per claim 6 for the manufacture of a medicament for the prevention and treatment of head lice infestation in humans.

41. (New) The user of a formulation as per claim 7 for the manufacture of a medicament for the prevention and treatment of head lice infestation in humans.

42. (New) The user of a formulation as per claim 8 for the manufacture of a medicament for the prevention and treatment of head lice infestation in humans.

43. (New) The user of a formulation as per claim 9 for the manufacture of a medicament for the prevention and treatment of head lice infestation in humans.